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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,664	02/06/2002	Chuan Li	ETI.PMMU.011502	8973

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EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/068,664

Applicant(s)

LI, CHUAN

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 6-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Claims 6-15 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 stand rejected under 35 U.S.C. 102(b) as being anticipated by Stemmer, for reasons of record set forth in paper No. 031604, mailed 16 March 2004.

Applicant argues, at the paragraph numbered “1)” bridging pages 3 and 4 of the response, that the processes of making the claims plasmids and the plasmid of Stemmer are different. However, Applicant relies upon limitations, i.e., process steps that are not recited in the instant claims. Furthermore, it is not apparent that such process step limitations, even if present in the claims, would have imparted a patentable distinction over the plasmid of Stemmer, as the claims are product-by-process claims, which are nonetheless construed as product claims.

In the same paragraph, Applicant argues that the plasmids of Stemmer were made using an existing plasmid as a template. However, the newly added limitation “without referring an existing plasmid as a template” is not clear (see the rejection under 35 USC § 112, second paragraph, below). This phrase could have been interpreted as meaning that no known elements or components of the plasmid were used, or that the entire sequence of the plasmid was unknown. Most importantly here, the phrase could have been interpreted as meaning that no direct polymerase synthesis, i.e., no DNA replication was performed using an existing plasmid as

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the replication template. Under this interpretation, the plasmid of Stemmer is clearly not excluded from the claims.

Point “2)”, at page 4 of the response, sets forth that the resulting plasmids of the claimed invention and Stemmer are different. However, as set forth above, these limitations are not present in the claims.

Point “3)”, bridging pages 4 and 5 of the response, sets forth that the uses of the plasmids of the invention and that of Stemmer are different. However, there are no limitations in the instant claims as to the intended use of the claimed plasmids which would impart any structural distinctions over the plasmid of Stemmer.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 stands, and newly amended claims 1 and 3 are now rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The inclusion of claims 1 and 3 in the instant rejection is as a result of the amendment to claim 1 (and therefore claim 3) “without referring an existing plasmid as a template”. As amended, the instant claims may now be interpreted as encompassing only plasmids wherein none of the elements or components of said

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plasmids were known in the art. As such, the problem of the lack of adequate understanding of protein structure-function relationships in the art, and the lack of such disclosure in the specification as well, is now applicable to the full scope of claim 1, i.e., the plasmids of claim 1 are now drawn only to those with completely new sequences. Clearly, to exclude all sequences known in the art would mean, by definition, that all of the sequences encompassed in the claimed plasmids were unknown in the art. Thus, they would have been described by function alone, which would have been insufficient given the inadequacy of understanding of protein structure-function relationships.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record set forth in Paper No. 031604, mailed 16 March 2004, and for new reasons set forth below, necessitated by amendment.

Claim 1, and therefore claims 2-5 which depend therefrom, remains rejected for the phrase "de novo synthesized plasmid", as the newly added phrase "without referring an existing plasmid as a template" does not clarify the claim, being itself unclear in meaning.

Claim 2 remains rejected as the phrase "the plasmid is not synthesized from an existing plasmid previously obtained from natural sources as a template" still remains unclear for the

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following reasons: 1) this phrase still could be interpreted as meaning that no sequence within it is identical to a sequence found in a natural plasmid, or as meaning that the sequences of the referenced, but undefined plasmid of the second part of the phrase, only, are excluded; 2) the reference to the existing plasmid acting (or not acting) as a template raises the question of whether the scope of the claim now encompasses the use of polymerase-driven DNA replication to replicate, i.e., copy the plasmid. See the rejection under 35 USC § 102(b), above.

Claim 3 remains rejected as the phrase “the plasmid is not synthesized from an existing plasmid previously obtained from recombinant sources as a template” still remains unclear for the following reasons: 1) this phrase still could be interpreted as meaning that no sequence within it is identical to a sequence found in a previously constructed plasmid, or as meaning that the sequences of the referenced, but undefined plasmid of the second part of the phrase, only, are excluded; 2) the reference to the existing plasmid acting (or not acting) as a template raises the question of whether the scope of the claim now encompasses the use of polymerase-driven DNA replication to replicate, i.e., copy the plasmid. See the rejection under 35 USC § 102(b), above.

In claim 1, and therefore claims 2-5 which depend therefrom, as noted above in this rejection, the phrase “without referring an existing plasmid as a template” is not clear. This phrase could have been interpreted as meaning that no known elements or components of the plasmid were used, that the entire sequence of the plasmid was unknown, or that no direct polymerase synthesis, i.e., no DNA replication was performed using an existing plasmid as the replication template. This new grounds is necessitated by the addition of this phrase by amendment.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jsk
October 14, 2004


JAMES KETTER
PRIMARY EXAMINER